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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,863	09/17/2003	Steven Walak	10123/00401	8458

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EXAMINER

WYSZOMIERSKI, GEORGE P

ART UNIT	PAPER NUMBER
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1742

MAIL DATE	DELIVERY MODE
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08/27/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/666,863

Applicant(s)

WALAK ET AL.

Examiner

George P. Wyszomierski

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 24 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-8, 15-19 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frantzen et al. (U.S. Patent 5,514,115) or over WIPO publication 02/36045.

Both Frantzen and WIPO '045 disclose medical devices (e.g. stents and catheters) made of Nitinol alloys and including portions that are in a martensitic state and portions in an austenitic state; see Frantzen column 2, line 31 thru column 4, line 26, or WIPO '045 page 8, lines 9-14 and page 10, lines 8-20. With respect to instant claim 2, any interface between the two such portions in the prior art meet the limitations of this claim. With respect to instant claims 6 and 7, note Frantzen column 3, lines 1-3. With respect to instant claims 8, 15, 18 and 19, the product-by-process limitations in these claims do not define a patentable product over those described in the prior art.

The prior art does not specifically recite the conditions regarding strain that the prior art devices are exposed to or the stability of the martensitic phase when deployed within a body. However, because the prior art devices are both made of the same materials as the claimed devices and are intended for use in substantially the same manner, it is a reasonable assumption that these parameters would also be the same or nearly so in the prior art and the claimed invention. Thus, a prima facie case of obviousness is established between the disclosures of Frantzen et al. or WIPO '045 and the presently claimed invention.

3. Claims 2, 9-13, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frantzen et al. or WIPO 02/36045, as above, either of which in view of Flomenblit et al. (U.S. patent 5,964,770).

Like Frantzen and WIPO '045, Flomenblit is directed to medical devices such as stents including both martensitic and austenitic portions. With respect to instant claim 2, Flomenblit column 4, lines 23-29 indicate that it was known in the art, at the time of the invention, to construct such devices having the limitations as recited in the instant claim. With respect to instant claims 9-13, 20 and 21, Flomenblit column 6, lines 58-67 indicates it was conventional in the art to employ Nitinol alloys including small amounts of one or more additional materials (besides Ni and Ti) as required by the instant claims. The precise manner by which these additional materials have come to be present in such devices does not patentably define a final product over those disclosed in the prior art. Thus, the disclosure of Frantzen et al. or WIPO '045, together with the teachings of Flomenblit et al., would have taught devices as presently claimed to one of ordinary skill in the art.

4. Claims 1, 3-8, 14-19, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle et al. (U.S. Patent 6,923,829).

Boyle discloses implantable medical devices made of nitinol, portions of which are in an austenitic phase and portions in a martensitic phase. With respect to instant claim 2, any interface between the two such portions in the prior art meet the limitations of this claim. With respect to instant claims 8, 15, 18 and 19, the product-by-process limitations in these claims do not define a product patentably distinct from the products of the prior art references. With respect to instant claims 14 and 23, Boyle column 9, lines 20-28 indicate that different portions of the material have different chemical compositions, as required by the instant claims.

The prior art does not specifically recite the conditions regarding strain that the prior art devices are exposed to or the stability of the martensitic phase when deployed in a body. However, because the prior art devices are both made of the same materials as the claimed devices and are intended for use in substantially the same manner, it is a reasonable assumption that these parameters would also be the same or nearly so in the prior art and the claimed invention. Thus, a prima facie case of obviousness is established between the disclosure of Boyle et al. and the presently claimed invention.

5. Claims 2, 9-13, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle et al. in view of Flomenblit et al.

Like Boyle, Flomenblit is directed to medical devices such as stents including both martensitic and austenitic portions. All aspects of Flomenblit as described in item no. 3 supra apply equally as well in this instance. Thus, the combined disclosures of Boyle et al. and Flomenblit et al. would have taught the present invention to one of ordinary skill in the art.

6. In a response filed July 9, 2007, Applicant alleges that the above rejections are based solely on assumptions or unsupported speculation by the examiner, and lack the evidence necessary to establish a prima facie case of obviousness. In response, the examiner's position is that the present situation is analogous to that of *In re Spada* (15 USPQ2d 1655, Fed.Cir. 1990). In *Spada*, the Court noted that if the prior art teaches an identical chemical structure, the properties an applicant discloses and/or claims are necessarily present. In the present case, all of the cited prior art (Frantzen, Boyle, WIPO '045) employ Ni-Ti alloy materials in substantially the same manner as are the Ni-Ti alloy materials set forth in the present specification, i.e. as certain medical devices to

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be deployed in a human body. Given the virtual identity of the materials and their uses in the prior art and the invention, the assumptions made by the examiner are far beyond the category of "unsupported speculation", but rather are reasonable conclusions that the properties of the prior art materials and those as claimed are most likely the same or nearly so. Applicant has not pointed to any specific distinction in size, shape, properties, or other physical aspects of the devices as claimed versus an equivalent parameter of any of the prior art devices.

7. The terminal disclaimer filed on July 9, 2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 6,890,350 has been reviewed and is accepted. The terminal disclaimer has been recorded.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to George Wyszomierski whose telephone number is (571) 272-1252. The examiner can normally be reached on Monday thru Friday from 8:00 a.m. to 4:30 p.m. Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Roy King, can be reached on (571) 272-1244. All patent application related correspondence transmitted by facsimile must be directed to the central facsimile number, (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


GEORGE WYSZOMIERSKI
PRIMARY EXAMINER
GROUP 1700

GPW
August 23, 2007